

## REMARKS

Claims 1-5, 8-10, 12, 46-56, and 58-60 were pending. No claims are amended or cancelled by this response. Accordingly, claims 1-5, 8-10, 12, 46-56, and 58-60 remain under consideration. Reconsideration and withdrawal of the rejections is requested in view of the following remarks.

Applicants respond to the claim rejections contained in the Office Action as follows:

### I. Rejections Based Upon Ewers Publication

Claims 1, 3-5, 8-10, 12, 46, 48-53, 55, 56, and 58-60 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Pub. No. 2005/0245945 to Ewers et al. ("Ewers"). In addition, claims 2 and 47 were rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over the Ewers publication, and claim 54 was rejected for obviousness over the Ewers publication in view of U.S. Patent Application Pub. No. 2002/0087098 to Iwami et al. ("Iwami").

Applicants traverse all of the foregoing claim rejections because the Ewers publication is not a proper prior art reference. The filing date of the Ewers publication is November 17, 2004, which is later than the July 1, 2003 filing date of the present application. Although the Ewers publication claims priority through several applications having filing dates prior to July 1, 2003 and/or the December 11, 2002 priority date of the present application, none of the earlier filed applications contains the subject matter relied upon in the Office Action to reject the present claims. All of the foregoing claim rejections must be withdrawn.

Moreover, the Ewers publication and the present application were, at the time of the invention of the present application, commonly assigned to USGI Medical Inc. Accordingly, under 35 U.S.C. § 103(c), the Ewers publication is not a proper reference under section 103. The rejections of claims 2, 47, and 54 must be withdrawn for this additional reason.

**II. Rejections Based Upon Martin, Hayhurst, et al.**

With the exceptions of claims 4 and 50, all of the pending claims were rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over the following combinations of patents and patent publications:

1. Claims 1, 9, 10, 12, 46, 51-53, 55, and 58-60 were rejected over the combination of U.S. Patent Application Pub. No. 2003/0167071 to Martin et al. ("Martin") in view of U.S. Patent No. 6,656,182 to Hayhurst ("Hayhurst");
2. Claims 2, 3, 5, 47, and 48 were rejected over the combination of Martin and Hayhurst, in further view of U.S. Patent Application Pub. No. 2002/058905 to Madrid et al. ("Madrid");
3. Claims 8 and 49 were rejected over the combination of Martin and Hayhurst, in further view of U.S. Patent Application Pub. No. 2003/0208211 to Kortenbach ("Kortenbach");
4. Claim 54 was rejected over the combination of Martin and Hayhurst, in further view of the Iwami publication;
5. Claim 56 was rejected over the combination of Martin and Hayhurst, in further view of U.S. Patent No. 6,921,378 to O'Keefe ("O'Keefe").

Applicants respectfully traverse these rejections on the grounds set forth below.

To establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

A. Martin and Hayhurst – Claims 1, 9, 10, 12, 46, 51-53, 55, and 58-60

The proposed combination of the Martin publication and Hayhurst patent does not support the claim rejections set forth in the Office Action because: (1) the proposed combination does not disclose or teach all of the limitations recited in the claims, and (2) the proposed combination would not have been obvious to a person skilled in the art.

1. Failure to Teach All Limitations

First, contrary to the contention stated at pages 10, 12, 13-14, 15, and 17 of the Office Action, the Martin publication does not teach or disclose “a coil on a front end of a shaft that is translatable disposed within a lumen” in the flexible tube. On the contrary, the Martin “coil 250” is one of the described forms of the “fastening element 102.” (Martin, paragraph 0060). Nowhere does the Martin publication describe or teach that the coil 250 (or fastening element 102) is “on a front end of a shaft” or that such shaft is “translatable disposed within a lumen” of the flexible tube (i.e., the “loading tool 200”). Nor does the Office Action identify where this feature can be found in the Martin publication.

Moreover, there is no reason why a person skilled in the art would have considered it obvious to modify the Martin coil 250 or fastening element 102 by including it on a front end of a shaft. The coil 250 / fastening element 102 is intended to be deployed by pushing it out of the distal end of the loading tool 200. (See Martin, paragraph 0057). The Office Action does not identify any teaching from any source that this operation would be facilitated by such a modification.

Finally, the Hayhurst patent does not correct the deficiencies of the Martin publication. Specifically, the Hayhurst patent does not teach or suggest “a coil on a front end of a shaft that is translatable disposed within a lumen” in the flexible tube.

It is fundamental that, in order to establish a *prima facie* case of obviousness, the Office Action must identify where and how the cited references teach or suggest all of the limitations of the claims. Failure to do so negates the conclusion of unpatentability for obviousness. Here, as set forth above, the Office Action fails to identify where and how the combination of the Martin publication and the Hayhurst patent teaches the limitation

of "a coil on a front end of a shaft that is translatable disposed within a lumen" in the flexible tube, which is recited in each of claims 1, 46, 55, 59, and 60.

Accordingly, the Office Action fails to state a *prima facie* case of obviousness as to claims 1, 46, 55, 59, and 60. Claims 9, 10, 12, 51-53, and 58 each depend from one of the foregoing claims, and each is patentable over the combination of Martin and Hayhurst for the same reasons. Applicants request withdrawal of the rejections of all of the foregoing claims.

## 2. Improper to Combine Martin and Hayhurst

As to the proposed combination of the Martin and Hayhurst devices, the Office Action states the following in support of the proposal:

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatable disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would have been obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatable disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

(Office Action, page 10). This proposed justification fails on several grounds.

First, the statement that "the devices of Martin and Hayhurst seek to solve a similar problem in the art" is far too vague and general an allegation to support the specific conclusion that it would have been obvious to modify the Martin device "such that the needle is translatable disposed within the tube of loading tool/catheter 200." Even assuming that Martin and Hayhurst seek to solve the stated problem, the conclusion that the specific modification would have been obvious does not follow, whether as a matter of mechanical compatibility, good engineering, or even basic logic.

Second, the allegation that both Martin and Hayhurst seek to solve the problem of "delivering a suture and anchor to a tissue site for a surgical procedure" is mistaken. It also misses the point. It is true that the Hayhurst patent is concerned with delivering an anchor to a tissue site. But the Martin publication relates to a very different objective of fastening sutures used in medical surgical procedures. There is no necessary (or obvious) connection between these objectives, and certainly nothing that would cause a person

skilled in the art to consider the proposed modification of the Martin device with the Hayhurst teachings to be obvious.

Finally, and ultimately, the proposed substitution of the Hayhurst needle and anchor into the Martin loading tool would not have been obvious to a person skilled in the art because there is no justifiable rationale for doing so:

- There is no recognized need or problem in the art that is common to both Martin and Hayhurst and that would have been solved by the proposed substitution;
- If the proposed substitution were made, the purpose for the Martin fastening element 102 would be defeated, *i.e.*, in combination with the Hayhurst device, the Martin device would no longer perform the function that it does separately;
- The Martin and Hayhurst devices are not mere variations of one another; and
- There is nothing in the Martin publication, the Hayhurst patent, or in the general knowledge in the art that would have taught, suggested, or motivated a person to modify the Martin device in the manner suggested in the Office Action.

For these additional reasons, Applicants request withdrawal of the rejections of claims 1, 9, 10, 12, 46, 51-53, 55, and 58-60

B. Martin, Hayhurst, and Madrid – Claims 2, 3, 5, 47, and 48

Claims 2, 3, and 5 each depend from claim 1, and claims 47 and 48 each depend from claim 46. Claims 1 and 46 are patentable over the combination of the Martin publication and the Hayhurst patent for the reasons set forth in Section II.A. above. The Madrid publication does not correct the deficiencies of the Martin publication and the Hayhurst patent. Accordingly, claims 2, 3, 5, 47, and 48 are patentable over the combination of Martin, Hayhurst, and Madrid.

In addition, claims 3 and 48 each recite that “the tube contains a plurality of slots disposed substantially perpendicular to a longitudinal axis of the tube.” The Madrid publication does not teach or suggest this feature. The portion of the Madrid publication identified in the Office Action (Madrid, paragraph 0046) teaches only that the tubular body 46 may include a braided layer (e.g., stainless steel) in or on the wall. This fails to teach or disclose the recited feature. For this additional reason, the rejections of claims 3 and 48 must be withdrawn.

C. Martin, Hayhurst, and Kortenbach – Claims 8 and 49

Claim 8 depends from claim 1, and claims 49 depends from claim 46. Claims 1 and 46 are patentable over the combination of the Martin publication and the Hayhurst patent for the reasons set forth in Section II.A. above. The Kortenbach publication does not correct the deficiencies of the Martin publication and the Hayhurst patent. Accordingly, claims 8 and 49 are patentable over the combination of Martin, Hayhurst, and Kortenbach.

In addition, the rationale stated in the Office Action for modifying “the device of the combined teaching of Martin and Hayhurst” is not sufficient to support the rejection. The Kortenbach helical coil 12 is a tissue fastening device intended to penetrate tissue. (See Kortenbach, paragraphs 0027-0028). In order to do so, the distal tip of the coil terminates in a point 16. The Martin fastening element 102, on the other hand, is intended to hold, adjust, and fasten one or more sutures, and is not intended to penetrate tissue. (Martin, paragraphs 0055-0056). There is, therefore, no reason why a person skilled in the art would have considered it obvious (or even useful) to provide a sharp tip (as per the Kortenbach tissue fastener) on the Martin suture fastening element.

For this additional reason, the rejections of claims 8 and 49 should be withdrawn.

D. Martin, Hayhurst, and Iwami – Claim 54

Claim 54 depends from claim 46, which is patentable over the combination of the Martin publication and the Hayhurst patent for the reasons set forth in Section II.A. above. The Iwami publication does not correct the deficiencies of the Martin publication and the Hayhurst patent. Accordingly, claim 54 is patentable over the combination of Martin, Hayhurst, and Iwami.

E. Martin, Hayhurst, and O’Keefe – Claim 56

Claim 56 depends from claim 55, which is patentable over the combination of the Martin publication and the Hayhurst patent for the reasons set forth in Section II.A. above. The O’Keefe patent does not correct the deficiencies of the Martin publication

and the Hayhurst patent. Accordingly, claim 56 is patentable over the combination of Martin, Hayhurst, and O'Keefe.

In addition, the rationale stated in the Office Action for the proposed combination of the O'Keefe patent with the Martin publication and the Hayhurst patent is not sufficient to support the rejection. The Examiner contends that:

O'Keefe teaches a drainage catheter having a plurality of slots extending substantially perpendicular to a longitudinal axis of the tube and present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases, and that these slots are of a curved shape. O'Keefe teaches that these slots are used to aid liquid flow through the retention end of the catheter. ('378, Col. 11, lines 4-11). Therefore placing slots in delivery catheter 520 at a distal end would be obvious to one of ordinary skill in the art as the catheter 520 performs a substantially identical function to that taught by O'Keefe.

(Office Action, pg. 22). But neither the Martin device nor the Hayhurst device is concerned with the objective of "aid[ing] liquid flow through the retention end of the catheter." Thus, there is nothing gained by adding the drainage slots to either of the Martin or Hayhurst devices. Once again, there is simply no reason why a person skilled in the art would have combined these references in the manner suggested. For this additional reason, the rejection of claim 56 should be withdrawn.

Based on the foregoing, the Office Action fails to establish a *prima facie* case that any of the claims are unpatentable for obviousness. Applicants respectfully request withdrawal of the rejections, and allowance of all of the pending claims.

Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Similarly, unless explicitly stated, nothing contained or not contained in this paper should be construed as an assent to any of the Examiner's stated grounds for rejecting the claims, including specifically the Examiner's characterization of the teachings of the cited art and the Examiner's contentions that any combinations of cited art would have been obvious. Rather, the present amendments to the claims and Remarks are an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

Application No.: 10/612,109  
Examiner: Hand, Melanie Jo

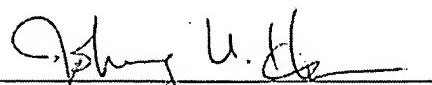
Attorney Docket No.: USGINZ02110

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No. USGINZ02110. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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